UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,522	03/09/2004	Joseph F. Poduslo	01017/30016A	2632

4743 7590 08/13/2008

MARSHALL, GERSTEIN & BORUN LLP
233 S. WACKER DRIVE, SUITE 6300
SEARS TOWER
CHICAGO, IL 60606

EXAMINER	
CHERNYSHEV, OLGA N	

ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
08/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/796,522	PODUSLO ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31,33-48 and 51-73* is/are pending in the application.

4a) Of the above claim(s) *47 and 51-66* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31, 33-46, 48 and 67-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claims 31, 43, 67 and 73 have been amended as requested in the amendment filed on May 22, 2008. Following the amendment, claims 31, 33-48 and 51-73 are pending in the instant application.

Claims 47 and 51-66 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Applicant timely traversed the restriction (election) requirement in the reply filed on February 27, 2006.

Claims 31, 33-46, 48 and 67-73 are under examination in the instant office action.

2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3. Applicant's arguments filed on May 22, 2008 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 31, 33-46, 48, 67, 68 and 72-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 31, 67 and 73, as currently presented, are vague and indefinite for recitation "improves or stabilizes one or more clinical features of a CNS disorder in a patient".

The metes and bounds of the recitation cannot be determined from the claims or the instant specification, as filed. For example, schizophrenia, a CNS disorder, is characterized by clinical features of delusions and hallucinations. Thus, the instant composition is claimed to improve or stabilize delusions or hallucinations in a patient, which renders the claimed subject matter ambiguous.

7. Claims 45 and 46 stand vague and indefinite for recitation of Aβ polypeptide with substitutions within the SEQ ID NO: 1. Applicant submits that the specification defines Aβ polypeptide as being represented by a molecule with substituted amino acids, "the broadest interpretation of the term " Aβ polypeptide" recited in claim 31 includes the substitutions recited in claims 45 and 46" (p. 9 of the Response). However, claim 45 specifically defines Aβ polypeptide as comprising residues 1-39 of SEQ ID NO: 1 and having substitutions, thus making the structure of the claimed embodiment mutually exclusive. Amendment to the claim to recite "Aβ polypeptide which differs from the peptide comprising amino acids 1-39 of SEQ ID NO: 1 by one or more substitutions of a single amino acid residue at position 5, 10, 13, 19 or 20" would obviate this ground of rejection.

8. Claims 48 and 72 stand vague and ambiguous for reciting specific characteristics of the claimed composition in terms related to "permeability", PS product, "the protein", "different brain regions" and adjustment of the reading after correction for reasons of record in section 10 of Paper mailed on February 22, 2008. Applicant argues that, "an assay and the terms used in the claims are not only described in the specification as originally filed (see, e.g., page 1, lines 16-18; page 13, line 28 through page 14, line 27; and page 15, lines 13-20) but also were well known in the art as of the filing date of the present application [Poduslo et al. articles].

Accordingly, Applicants respectfully submit that one of skill in the art would not find claims 48 or 72 vague and/or ambiguous" (p. 9 of the Response). Applicant's argument has been given careful consideration but is not persuasive for the following reasons.

The instant claimed invention is directed to a product, specifically a therapeutic composition comprising two polypeptides linked to each other, which defines its distinguishing inventive property. As fully explained in the previous office action of record, the presence of the limitation, which further characterizes the claimed product by reference to its ability to cross BBB while not specifically pointing out as how to distinguish those compositions that meet the limitations of claims 48 and 72 from the ones that do not, makes the claimed subject matter vague and ambiguous.

Section 112 of the patent statute describes what must be contained in the patent specification and mandates that it must contain "a written description of the invention." 35 U.S.C. §112 ¶ 1. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Further, the second paragraph of 35 U.S.C. 112 recites the following two separate requirements:

(A) the claims must set forth the subject matter that applicants regard as their invention; and

(B) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant.

MPEP 2171 specifically points out that an "essential purpose of patent examination is to determine whether or not the claims are precise, clear, correct, and unambiguous. The uncertainties of claim scope should be removed, as much as possible, during the examination process".

The Examiner maintains that claims 48 and 72 are indefinite because neither the claims nor the instant specification provide clear delineation of the material limitations of the claimed products so that one skilled is able to distinguish the claimed subject matter from compositions known in prior art or claimed in claim 31, for example. Alternatively, the claims do not satisfy the written description requirement because a skilled practitioner cannot envision the structure of the claimed compositions and distinguish the product of claim 48 from the product of claim 31, for example.

9. Claims 33-44, 68, 70 and 71 are indefinite for being dependent from indefinite claim.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 31, 33-35, 43, 48, 69 and 72-73 stand rejected under 35 U.S.C. 102(b) as being anticipated by Solomon et al., 1997, for reasons of record in section 13 of Paper mailed on February 22, 2008.

Applicant traverses the rejection on the premises that Solomon article does not teach "a composition comprising sterile, pharmaceutically acceptable carrier or excipient" and states that, "Solomon described treating PC 12 cells cultured in a DMEM cell culture medium, containing components which the skilled artisan would recognize as inappropriate in a carrier or excipient

for a therapeutic composition" (p. 10 of the Response). Applicant's arguments have been fully considered but are not persuasive for reasons that follow.

The fact that composition comprising Aβ linked to anti-Aβ antibody of Solomon et al. was indeed sterile is self-obvious as it was used to treat cell cultures *in vitro* for at least two days. Further, the medium used to culture PC12 cells is compatible with physiological conditions, and not incompatible with pharmaceutical use. Since the instant specification does not provide any limiting definitions of pharmaceutical carriers, the prior art's culture medium would appear to be encompassed by the broadest reasonable definition of a "pharmaceutical carrier".

For reasons of record in previous communication of record and reasons above, the instant rejection is maintained.

12. Claims 31, 33 and 42-43, 45-46, 48, 67-68 and 70-73 stand rejected under 35 U.S.C. 102(b) as being anticipated by Schenk, 1999, WO99/27944 for reasons of record as applied to claims 31 and 42-45 in section 5 of Paper mailed on August 28, 2007 and section 20 of Paper mailed on February 22, 2008.

At p. 11 of the Response, Applicant argues that, "Schenk does not anticipate the claimed invention because Schenk failed to disclose or suggest an Aβ polypeptide linked to a therapeutic non-Aβ polypeptide, wherein the non-Aβ polypeptide improves or stabilizes one or more clinical features of a CNS disorder in a patient, as recited in claim 31, 67 or 73". Applicant's argument has been fully considered but is not persuasive because the limitation cited by Applicant as distinguishing feature is addressed by the Examiner in section 6 of the instant office action as being vague and indefinite. MPEP 2111 [R-1] specifically states that when analyzing the scope of the claimed subject matter, the teachings of the specification are to be taken into account

because the claims are to be given their broadest reasonable interpretation that is consistent with the specification (see MPEP 2111 [R-1], which states that claims must be given their broadest reasonable interpretation

"During patent examination, the pending claims must be "given *>their< broadest reasonable interpretation consistent with the specification." *In re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Applicant always has the opportunity to amend the claims during prosecution, and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550- 51 (CCPA 1969)".

Thus, since the material limitations of the claimed composition are fully disclosed by Schenk document, then the art anticipates and the instant rejection is maintained.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 36-40 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solomon et al., 1997 for reasons of record in section 16 of Paper mailed on February 22, 2008.

Applicant traverses the rejection on the premises that are similar to the traversal of 102(b) rejection of claims 31, 33-35, 43, 48, 69 and 72-73 in section 11 above. "As discussed above in Section III, Solomon neither discloses or suggests that its composition comprises a sterile pharmaceutically-acceptable carrier or excipient or that the antibody in the inmmnocomplex improves or stabilizes one or more clinical features of a CNS disorder in a patient as defined in the specification and in claim 31, from which claims 36-40 and 44 depend" (p. 13 of the Response). Applicant's arguments have been fully considered but are not persuasive for the same reasons as fully explained in section 11 above. Briefly, Solomon et al. reference teaches sterile and pharmaceutically acceptable carrier for the composition, which is structurally identical to the one of claims 31, 33-35, 43, 48, 69 and 72-73, thus making the instant invention of claims 36-40 and 44 obvious.

For reasons of record in previous communication of record and reasons above, the instant rejection is maintained.

Allowable Subject Matter

15. Claim 41 directed to therapeutic composition comprising an amyloid beta (Aβ) polypeptide linked to a monoclonal anti-Aβ antibody wherein the antibody is polyamine modified and a sterile pharmaceutically acceptable carrier or excipient, would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

16. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

August 12, 2008

/Olga N. Chernyshev, Ph.D./
Primary Examiner, Art Unit 1649